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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,814

05/11/2005

Rainer Hipfel

P67564US1

4911

136 7590 03/09/2009

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

03/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

1) Claims 1, 2 and 5 to 32 are pending in the instant application. Claims 1, 2, 6 to 8, 11 to 25 and 30 to 32 have been amended and claims 3 and 4 have been canceled as requested by Applicant in the correspondence filed 11 December of 2008.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

4) Claims 11 to 32 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08 February of 2008.

### ***Claim Rejections - 35 USC § 112***

5) Claims 1, 2 and 5 to 10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record as applied to claims 1 to 10 in section 6 of the office action mailed 26 May of 2006.

These claims are directed to a method of diagnosing or monitoring the progression of a neurodegenerative disease in a subject by measuring the expression

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level of a protein identified in the specification as “SCN2A” in a sample from that subject and comparing that expression level to a reference value. The claims are not enabled because the specification fails to disclose an established nexus between the expression level of “SCN2A” and the presence or progression of neurodegenerative diseases in general. Further, the specification fails to show any difference between the expression level of “SCN2A” in living subjects suffering from any particular neurodegenerative disease or disorder and the expression level of that protein in living subjects that are free of that disease or disorder. And finally, whereas there is no “Table 1” or “Table 2” in the instant application, the value range for the expression level of “SCN2A” in post mortem brain samples from Alzheimer’s diseased patients and healthy individuals, as given on pages 33 and 34 of the instant specification overlap, indicating that the level of expression of “SCN2A” in a post mortem brain may, or may not be indicative of the presence of Alzheimer’s disease in the corpse from which it was derived. In summary, the instant claims are not enabled because the instant specification provides no evidence that the expression level of “SCN2A”, as measured in sample and, in particular, cerebrospinal fluid, differs between healthy living individuals in general and in living individuals suffering from a neurodegenerative disease and, in particular, Alzheimer’s diseased.

Applicant’s argument that the claims are now limited to Alzheimer’s disease is not supported by the claims of record and, even if it was, such a limitation would not avoid the above rejection.

***Claim Rejections - 35 USC § 102***

6) Claims 1, 5 and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Planells-Cases et al. publication (Biophys. J. 78:2878-2891, 2000), cited by Applicant) for those reasons of record in section 8 of the office action mailed 26 May of 2006. As stated therein, Figure 2A on page 2882 of the Planells-Cases et al. publication anticipates the instant claims because it disclose a method of diagnosing a disease that results in massive apoptosis (see abstract) by measuring and comparing the expression level of SCNA2 mRNA from a subject in which the SCNA2 gene that has been disrupted a control subject not suffering from the genetic disruption.

As indicated above, Applicant's traversal of this rejection on the premise that the claims are now limited to Alzheimer's disease is not supported by the claims of record.

#### ***Claim Rejections - 35 USC § 103***

7) Claims 2 and 8 to 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Planells-Cases et al. publication (Biophys. J. 78:2878-2891, 2000), cited by Applicant) for those reasons of record as applied to claims 2, 3 and 8 to 10 in section 10 of the office action mailed 26 May of 2006.

#### ***Response to Arguments***

8) Applicant's arguments filed 11 December of 2008 have been fully considered but they are not persuasive.

#### ***Conclusion***

9) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/  
Primary Examiner, Art Unit 1649